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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/937,756

09/25/1997

DAVID C. RUEGER

JJJ-P06-504

2132

7590

02/17/2005

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EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/937,756

Applicant(s)

RUEGER ET AL

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97,99 and 105-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97,99 and 105-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12-3-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The amendment filed 11-5-04 has been entered into the record and has been fully considered. The IDS submitted 12-3-04 has been entered into the record and has been fully considered.
2. The Examiner notes the submission of Terminal Disclaimers for Patents 6,194,376, 6,723,698 and 6,506,729, which have been accepted. However, it is noted that disclaimer over US 6,288,031 has not been submitted.
3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.
5. Claims 97, 99 and 105-111 are pending.

Specification/Sequence Compliance

6. The disclosure is objected to because of the following informalities: The case fails to comply fully with the sequence rules. There is no copy of the computer readable format of the sequence listing. Applicant's may wish to submit a letter requesting transfer of the computer readable format from the parent case with the required statement that the paper and CRF copies are the same and no new matter is presented.

Appropriate correction is required.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37

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CFR 1.821 through 1.825 for the reason(s) set forth above. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 97, 99 and 105-111 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S.

Patent No. 6,288,031. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to a species of decreasing neuronal cell death associated with neuropathy and/or chemical or physical injury which anticipates the instantly claimed genus. The species is of reducing an inflammatory response in a patient with neural tissue damage which is recognized as providing for decreased neuronal cell death as in ischemic-reperfusion tissue injury, hypoxic tissue injury and hyperoxic tissue injury as in claim 4. The tissue is of neural tissue as in claim 6. Also noted are the neurodegenerative diseases as in claim 7. The

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treatments each provide for administration in contact with the same morphogenic compounds and the same neuronal cells, see in particular claims 1-3. Thus, the '031 claims render obvious instant claims as the species disclosed render obvious instant genus.

Applicants request in the response of 11-5-04, withdrawal of the double patenting rejection based upon submission of a terminal disclaimer. No comments as to the correctness of the rejection are noted.

Applicant's arguments filed 11-5-04 have been fully considered but are not persuasive. It is noted that disclaimer over US 6,288,031 has not been submitted. Therefore rejection is maintained as set forth in MPEP 804.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 97, 99 and 105-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendment of 11-5-04 introduces the limitation "at risk of such cell death". The recitation appear to further limit or narrow those neuronal cells to be contacted, yet

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no support for the recitation has been provided and no support for the apparent narrowing can be found. Accordingly the recitation constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 97, 99 and 105-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation at risk of such cell death is indefinite to the artisan as there is no identified or requisite means for assessing those neurons that are at risk from those that are not. The artisan cannot discern those neurons intended to be included or excluded by the term.

Status of Claims

10. No claims are allowed.
11. Applicants are reminded of their duty to disclose. The Examiner notes multiple co-pending applications via instant Inventors, the status of which may change during prosecution on the merits.
12. The enablement rejection is withdrawn in view of applicant's amendments and further notation of subsequent art that lends credence to support enablement of the claimed invention. In particular the finding that multiple morphogens stimulate NCAM/L1 and that NCAM/L1 expression is associated with neuronal survival, see for example, Hulley et al., J. of Neurosci. Res., 1998 July 15, 53(2):129-34, Chen et al., J. of Neurobiol., 1999 Feb. 15, 38(3):428-39, Chao et al., Neurobiol. Of aging, 2003 Jan-

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Feb., 24(1):105-16 and Ditlevsen et al., J. of Neurochem., 2003 Feb., 84(3):546-56.

13. WO 92/00382 is not deemed to anticipate or render obvious instant claims based upon the following analysis of the facts. The teachings of the reference at pp. 13-14 paragraph spanning are particularly noted. Activin is outside of instant structural limitations of the claims and thus disclosure of it as a neuronal survival factor does not anticipate or render obvious instant invention. The reference notes that "if GDF-1 functions as a growth-stimulatory factor for specific cell types, other potential therapeutic uses will be apparent" and that "if GDF-1 possesses a similar activity as is indicated by its specific expression in the central nervous system, GDF-1 will likely prove useful in vitro for maintaining neuronal cultures for eventual transplantation or in vivo for rescuing neurons following axonal injury or in disease states leading to neuronal degeneration." It is pertinent to note that GDF-1 prior to applicants filing date was not disclosed as possessing any activities to specific cell types, particularly neurons and particularly with relation to neuronal survival. Accordingly, the WO 92/00382 reference and the mere notation of GDF-1's expression in neuronal cells as recognized in the prior art, is not deemed to be sufficiently enabling to anticipate or render obvious the instantly claimed invention for use of the factor GDF-1 or related BMP molecules in a method for decreasing neuronal cell death.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

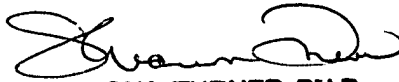
15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.

Sharon L. Turner, Ph.D.
February 15, 2005


SHARON L. TURNER, PH.D.
PATENT EXAMINER
2-15-05